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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/826,316	04/19/2004	Olivier De La Charriere	1016800-000678	1068
21839 7590 10/05/2007 BUCHANAN, INGERSOLL & ROONEY PC POST OFFICE BOX 1404 ALEXANDRIA, VA 22313-1404			EXAMINER FLOOD, MICHELE C	
			ART UNIT 1655	PAPER NUMBER
			NOTIFICATION DATE 10/05/2007	DELIVERY MODE ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

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Office Action Summary

Application No.

10/826,316

Applicant(s)

CHARRIERE ET AL.

Examiner

Michele Flood

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 03 July 2007.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 40-66,77-116 and 137-145 is/are pending in the application.
- 4a) Of the above claim(s) 97-106 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 77-96,107-116 and 137-145 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____

DETAILED ACTION

Acknowledgment is made of the receipt and entry of the amendment filed on July 3, 2007 with the cancellation of Claims 67-76 and 117-136, and the addition of newly submitted Claims 137-145.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claims 77-96, 107-116 and 137-145 are under examination.

Claim Rejections - 35 USC § 103

Claims 77- 80, 83-90, 107-110, 113-115 and 137-141 are rejected under 35 U.S.C. 103(a) as being unpatentable over Klett-Loch (AA; US 6,013,279) in view of Oury (N). Newly applied as necessitated by amendment.

Applicant claims a regime or regimen for increasing hair density comprising orally administering to an individual in need of such treatment, for such period of time as required to elicit the desired effect by increasing the number of hairs per cm² of scalp, a vitamin/metal salt cosmetic/pharmaceutical composition comprising a thus effective amount of admixture of the antioxidants vitamin A, vitamin C, vitamin E and also zinc and selenium salts, formulated into a cosmetically/pharmaceutically acceptable vehicle, diluent or carrier therefor.

Klett-Loch teaches a method for increasing hair density comprising administering to a person in need thereof a composition consisting essentially of vitamin B; the antioxidant vitamins A (beta-carotene), C (calcium ascorbate, a salt of ascorbic acid)

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and E (alpha-tocopherol); selenium (selenium yeast); and, the sulfur-containing amino acid, cystine. See patent claims. The composition taught by Klett-Loch may be in the form of an emulsion, tablets, capsules, or gelatin capsules. See Column 4, line 34 to Column 5, line 44. In Column 2, lines 39-54, Klett-Loch teaches that the referenced composition stimulates the growth of hair; prevents or eliminates the loss of hair; accelerates multiphase, lengthy regrowth process, while avoiding a shrinkage of the hair follicles and thereby increasing hair density, preserves the health of the hair; improves the basic health of the hair; and increases hair density by either oral or topical application.

The teachings of Klett-Loch are set forth above. Klett-Loch teaches the instantly claimed invention except for wherein the admixture comprises a zinc salt, an iron salt, and a magnesium salt. However, it would have been obvious to one ordinary skill in the art to add the instantly claimed ingredients to the method of increasing hair density taught by Klett-Loch to provide the instantly claimed regime or regimen because at the time the invention was made Oury taught an oral composition for use against hair loss comprising effective amounts of vitamin B, vitamin C, L-cysteine, magnesium chloride, iron gluconate, vitamin E and zinc sulfate. At the time the invention was made one of ordinary skill in the art would have been motivated and one would have had a reasonable expectation of success to add the composition taught by Oury to the composition used in the method for increasing hair density taught by Klett-Loch to provide the instantly claimed regime or regimen because Oury taught that the oral administration of a composition comprising effective amounts of the antioxidant

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vitamins, vitamin C and vitamin E, vitamin B and salts of zinc, iron, and magnesium was useful in methods of treatment against hair loss, as well as for methods for treating brittle nails, like the beneficial functions of the composition used in the method taught by Klett-Loch. Given the foregoing, one would have had a reasonable expectation that the addition of the instantly claimed ingredients to the method taught by Klett-Loch would improve the quality and/or appearance of a head of hair.

With regard to the claim limitation for administration of the claim-designated admixture for a period of time to elicit a desired effect, the adjustment of particular conventional working conditions (e.g., determining a result-effective means of administering the claimed ingredients for a period of time to induce a therapeutic effect), is deemed merely a matter of judicious selection and routine optimization which is well within the purview of either one of ordinary skill in the art or the skilled artisan. Thus, as each of the references indicates that the various ingredients, process steps and experimental parameters used in the claimed method are result variables, they would have been routinely optimized by one of ordinary skill in the art in practicing the invention disclosed by each of the references.

Accordingly, the claimed invention was *prima facie* obvious to one of ordinary skill in the art at the time the invention was made, especially in the absence of evidence to the contrary.

Claims 77, 78, 83-88, 87, 88, 93-95, 107, 108, 113-115 and 137-141 are rejected under 35 U.S.C. 103(a) as being unpatentable over Klett-Loch (AA; US 6,013,279) in view of Neve et al. (U) and Shakhtmeister et al. (V) as made evident by the teachings of Medical Dictionary Online (W). Newly applied as necessitated by amendment.

Klett-Loch teaches a method for increasing hair density comprising administering to a person in need thereof a composition consisting essentially of vitamin B; the antioxidant vitamins A (beta-carotene), C (calcium ascorbate, a salt of ascorbic acid) and E (alpha-tocopherol); selenium (selenium yeast); and, the sulfur-containing amino acid, cystine. See patent claims. The composition taught by Klett-Loch may be in the form of an emulsion, tablets, capsules, or gelatin capsules. See Column 4, line 34 to Column 5, line 44. In Column 2, lines 39-54, Klett-Loch teaches that the referenced composition stimulates the growth of hair; prevents or eliminates the loss of hair; accelerates multiphase, lengthy regrowth process, while avoiding a shrinkage of the hair follicles and thereby increasing hair density, preserves the health of the hair; improves the basic health of the hair; and increases hair density by either oral or topical application.

The teachings of Klett-Loch are set forth above. Klett-Loch teaches the instantly claimed invention except for wherein the admixture comprises zinc sulfate. However, it would have been obvious to one of ordinary skill in the art to add the instantly claimed ingredient to the method of increasing hair density taught by Klett-Loch to provide the instantly claimed regime or regimen because at the time the invention was made both Neve and Shakhtmeister taught that the oral administration of compositions comprising

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an effective amount of zinc sulfate for a certain period of time beneficially increases hair growth and was useful in methods of treating hair loss, such as alopecia. At the time the invention was made, one of ordinary skill in the art would have been motivated and one would have had a reasonable expectation of success to add zinc sulfate to the method of increasing hair density taught by Klett-Loch to provide the instantly claimed regime or regimen because Neve taught that the oral administration of 200 mg of zinc sulfate three times a day reversed hair loss and stimulated regrowth of hair; and, Shakhtmeister taught that the oral administration of Zincteral (zinc sulfate, see reference W) three times a day was useful in the treatment of various forms of alopecia by affecting regrowth of hair. Given the foregoing, one would have had a reasonable expectation that the addition of the instantly claimed ingredients to the method taught by Klett-Loch would improve the quality and/or appearance of a head of hair, as well as treating conditions of alopecia.

With regard to the claim limitation for administration of the claim-designated admixture for a period of time to elicit a desired effect, the adjustment of particular conventional working conditions (e.g., determining a result-effective means of administering the claimed ingredients for a period of time to induce a therapeutic effect), is deemed merely a matter of judicious selection and routine optimization which is well within the purview of either one of ordinary skill in the art or the skilled artisan. Thus, as each of the references indicates that the various ingredients, process steps and experimental parameters used in the claimed method are result variables, they would

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have been routinely optimized by one of ordinary skill in the art in practicing the invention disclosed by each of the references.

Accordingly, the claimed invention was *prima facie* obvious to one of ordinary skill in the art at the time the invention was made, especially in the absence of evidence to the contrary.

Claims 77- 80, 83-90, 107-110, 113-115 and 137-141 are rejected under 35 U.S.C. 103(a) as being unpatentable over Klett-Loch (AA; US 6,013,279) and Oury (N) in view of Balch et al. (U), Navarra et al. (U1) and Williams et al. (A*). Newly applied as necessitated by amendment.

The combined teachings of Klett-Loch and Oury are set forth above. The combined teachings of Klett-Loch and Oury teach the instantly claimed invention except for wherein the admixture comprises a salt of cooper and a salt of manganese. However, it would have been obvious to one of ordinary skill in the art to add the instantly claimed ingredient to the method of increasing hair density taught by the combined teachings of Klett-Loch and Oury to provide the instantly claimed regime or regimen because at the time the invention was made the instantly claimed ingredients were known in the art for their beneficial functional effects, as evidenced by the teachings of Balch, Navarra and Williams. Firstly, Balch beneficially teaches that a deficiency in zinc may result in hair loss, on page 29, under "*Zinc*". Moreover, on page 24, under "*Copper*", Balch teaches that copper is involved in hair coloring, works in balance with zinc and vitamin C, and aids in the production of blood; on page 25 under

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"*Iron*", Balch teaches that a lack of iron in the body may result in brittle hair and hair loss; on page 26 under "*Magnesium*", Balch teaches that magnesium is a vital catalyst in enzyme activity and maintains the body's pH balance; and, on page 26, under "*Manganese*", Balch teaches that manganese is essential for iron deficiency, is needed for utilization of vitamin B1 (thiamine) and vitamin E. Secondly, Navarra teaches that salts of iron (see pp. 105-108), salts of magnesium (see pp. 127-128), and salts of copper (see pp. 57-58) are pharmaceutically acceptable forms of the metallic elements for use in the making of cosmetic/pharmaceuticals for administration to humans; and, Williams teaches that salts of magnesium and manganese are useful in the making of vitamin/metal salt compositions comprising antioxidant vitamins, such as vitamins A, C and E, and vitamin B, for human consumption. At the time the invention was made, one of ordinary skill in the art would have been motivated and one would have had a reasonable expectation of success to add the instantly claimed ingredients to the method taught by the combined teachings of Klett-Loch and Oury to provide the instantly the instantly claimed regime or regimen because Balch taught that intake and absorption of zinc by humans are essential in maintaining the proper concentration of vitamin E in blood, and that zinc also increases the absorption of vitamin A; and, furthermore Balch taught that the intake of proper amounts of copper, iron, magnesium and manganese, as well as zinc, is important in the absorption of vitamins and maintaining the proper chemical balance of the body, maintaining overall health of the human body, as well as the health of the hair of individual, (see page 12); and both Navarra and Williams suggested that salts of iron, magnesium, copper and manganese

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are desirable in the making of cosmetic/pharmaceuticals intended for the administration to humans for mineral supplementation because they are generally non-toxic and well absorbed by the human body and tolerated by humans when administered in therapeutic dose amounts; and, furthermore, like Balch, Navarra taught that vitamin A, vitamin C, vitamin B, iron, copper, zinc are particular determinants of hair loss, hair growth, hair baldness, hair growth pattern, and the appearance of hair (see page 96). Given the foregoing, one would have had a reasonable expectation that the addition of the instantly claimed ingredients to the method taught by the combined teachings of Klett-Loch and Oury would improve the quality and/or appearance of a head of hair.

With regard to the claim limitation for administration of the claim-designated admixture for a period of time to elicit a desired effect, the adjustment of particular conventional working conditions (e.g., determining a result-effective means of administering the claimed ingredients for a period of time to induce a therapeutic effect), is deemed merely a matter of judicious selection and routine optimization which is well within the purview of either one of ordinary skill in the art or the skilled artisan. Thus, as each of the references indicates that the various ingredients, process steps and experimental parameters used in the claimed method are result variables, they would have been routinely optimized by one of ordinary skill in the art in practicing the invention disclosed by each of the references.

Accordingly, the claimed invention was *prima facie* obvious to one of ordinary skill in the art at the time the invention was made, especially in the absence of evidence to the contrary.

Claims 86, 96 and 116 are rejected under 35 U.S.C. 103(a) as being unpatentable over Klett-Loch (AA; US 6,013,279), Neve et al. (U) and Shakhtmeister et al. (V) in view of Gulmagarashvili et al. (O) and Amer (B*). Newly applied as necessitated by amendment.

The combined teachings of Klett-Loch, Neve and Shakhtmeister are set forth above. The combined teachings of Klett-Loch, Neve and Shakhtmeister teach the instantly claimed invention except for wherein the admixture comprises sodium selenite. However, it would have been obvious to one of ordinary skill in the art to either add sodium selenite to the method composition or to replace the selenite salt used in the method of increasing hair density taught by the combined teachings of Klett-Loch, Neve and Shakhtmeister to provide the instantly claimed regime or regimen because at the time the invention was made Gulmagarashvili taught an aqueous suspension of trace elements with addition of vitamins A and E, namely: 0.25% neoselenium aqueous solution (sodium selenite), 0.2% copper sulfate aqueous solution, 0.5% zinc oxide aqueous suspension, and 0.1% silicon aqueous suspension that was useful in the treatment of alopecia; and, Amer taught an antioxidant composition comprising sodium selenite and beta-carotene intended for oral administration. At the time the invention was made one of ordinary skill in the art would have been motivated and one would have been motivated to either add sodium selenite to the method composition or to replace the selenite salt used in the method of increasing hair density taught by the combined teachings of Klett-Loch, Neve and Shakhtmeister to provide the instantly claimed regime or regimen because Gulmagarashvili taught that admixtures comprising

therapeutic amounts of antioxidant vitamins such as vitamin A and vitamin, when combined with sodium selenite was useful in the treatment of alopecia; and Amer taught sodium selenite was non-toxic and suggested that sodium selenite and selenium-yeast, such as the selenium containing yeast taught by Klett-Loch were functional equivalents, one for the other; thus, it would have been *prima facie* obvious to replace selenium form for the other; and, thus would have had a reasonable expectation of success that such addition would improve the quality and/or appearance of a head of hair.

With regard to the claim limitation for administration of the claim-designated admixture for a period of time to elicit a desired effect, the adjustment of particular conventional working conditions (e.g., determining a result-effective means of administering the claimed ingredients for a period of time to induce a therapeutic effect), is deemed merely a matter of judicious selection and routine optimization which is well within the purview of either one of ordinary skill in the art or the skilled artisan. Thus, as each of the references indicates that the various ingredients, process steps and experimental parameters used in the claimed method are result variables, they would have been routinely optimized by one of ordinary skill in the art in practicing the invention disclosed by each of the references.

Accordingly, the claimed invention was *prima facie* obvious to one of ordinary skill in the art at the time the invention was made, especially in the absence of evidence to the contrary.

Claims 141-145 are rejected under 35 U.S.C. 103(a) as being unpatentable over Klett-Loch (AA; US 6,013,279), Oury (N), Balch et al. (U), Navarra et al. (U1) and Williams et al. (A*) in view of Gulmagarashvili et al. (O) and Amer (B*). Newly applied as necessitated by amendment.

The combined teachings of Klett-Loch, Oury, Balch, Navarra and Williams are set forth above. The combined teachings of Klett-Loch, Oury, Balch, Navarra and Williams teach the instantly claimed invention except for wherein the admixture comprises sodium selenite. However, it would have been obvious to one of ordinary skill in the art to either add sodium selenite to the method composition or to replace the selenite salt used in the method of increasing hair density taught by the combined teachings of Klett-Loch, Oury, Balch, Navarra and Williams to provide the instantly claimed regime or regimen because at the time the invention was made Gulmagarashvili taught an aqueous suspension of trace elements with addition of vitamins A and E, namely: 0.25% neoselenium aqueous solution (sodium selenite), 0.2% copper sulfate aqueous solution, 0.5% zinc oxide aqueous suspension, and 0.1% silicon aqueous suspension that was useful in the treatment of alopecia; and, Amer taught an antioxidant composition comprising sodium selenite and beta-carotene intended for oral administration. At the time the invention was made one of ordinary skill in the art would have been motivated and one would have been motivated to either add sodium selenite to the method composition or to replace the selenite salt used in the method of increasing hair density taught by the combined teachings of Klett-Loch, Oury, Balch, Navarra and Williams to provide the instantly claimed regime or regimen because

Gulmagarashvili taught that admixtures comprising therapeutic amounts of antioxidant vitamins such as vitamin A and vitamin, when combined with sodium selenite was useful in the treatment of alopecia; and Amer taught sodium selenite was non-toxic and suggested that sodium selenite and selenium-yeast, such as the selenium containing yeast taught by Klett-Loch were functional equivalents, one for the other; and thus, it would have been *prima facie* obvious to replace one selenium functional equivalent for the other wherein the selenium compounds were each known in the art to have the same pharmacodynamic activity and known in the art to provide the same beneficial functional effect.

With regard to the claim limitation for administration of the claim-designated admixture for a period of time to elicit a desired effect, the adjustment of particular conventional working conditions (e.g., determining a result-effective means of administering the claimed ingredients for a period of time to induce a therapeutic effect), is deemed merely a matter of judicious selection and routine optimization which is well within the purview of either one of ordinary skill in the art or the skilled artisan. Thus, as each of the references indicates that the various ingredients, process steps and experimental parameters used in the claimed method are result variables, they would have been routinely optimized by one of ordinary skill in the art in practicing the invention disclosed by each of the references.

Accordingly, the claimed invention was *prima facie* obvious to one of ordinary skill in the art at the time the invention was made, especially in the absence of evidence to the contrary.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michele Flood whose telephone number is 571-272-0964. The examiner can normally be reached on 7:00 am - 3:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Terry McKelvey can be reached on 571-272-0775. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.


MICHELE FLOOD
PRIMARY EXAMINER

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Primary Examiner
Art Unit 1655

MCF
October 1, 2007